REMARKS

The Examiner's attention is directed to the Information Disclosure Statement mailed September 3, 2003 and to the Supplemental Information Disclosure Statement mailed September 15, 2003, neither of which appears to have been considered by the Examiner. Copies of such Information Disclosure Statements, and the return postcard stamped by the Patent and Trademark Office on September 8, 2003 pertaining to the Information Disclosure Statement and the return postcard stamped by the Patent and Trademark Office on October 3, 2003 pertaining to the Supplemental Information Disclosure Statement, are enclosed herewith. Applicants request that the Examiner consider such Information Disclosure Statements and indicate such consideration in the next action.

Claims 2, 5 and 12-15 have been amended to make them more readable, such amendments not intended to limit the claims in response to any cited references. Nonelected Claims 16-19 have been cancelled.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Barath (U.S. Patent No. 5,196,024). Claims 2-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Barath, Vigil et al. (U.S. Patent No. 5,320,634) and/or Kaplan et al. (U.S. Patent No. 5,336,178). Reconsideration of these claims is respectfully requested.

Barath discloses a cutting balloon catheter having a catheter shaft (1), and a lumen with an inflatable balloon (2), in its inflated state, at the distal end. In the catheter shaft, there is a central lumen (3) and a coaxial lumen (4). The central lumen accommodates the catheter guide wire and provides a channel for injection of the contrast material. The coaxial lumen serves to inflate the balloon through side holes (5). Sharp longitudinal processes or cutting edges (6) protrude parallel with the longitudinal axis of the surface of the balloon. Col. 3, line 62 through Col. 4, line 3. The balloon shown in FIG. 2 is inflated (2) and the cutting edges (6) penetrate into the vessel wall (7, 8) making longitudinal cuts with sharp margins (11) in the vessel wall. Col. 4, lines 18-21. FIG. 7 and its cut-out FIG. 8 show a metallic cutting edge (6) which is sitting on a metallic plate (13). The metallic plate and edges are discrete sections and mounted onto the balloon surface in a row parallel with the longitudinal axis of the balloon, thereby providing articulation to the device. The edges are covered by folds (14) of the balloon in the deflated state. Col. 4, lines 54-61. FIG. 14 shows an embodiment in which the cutting edges are formed of specially shaped wires (19) sitting in grooves (14) on the balloon (2) surface. As shown in

FIG. 15, the distal ends (20) of the wires are fixed to the distal part of the catheter shaft (21) while the proximal end of the wire (22) goes underneath a ring (23) placed around the catheter shaft (1). The wires can freely slide under the ring. The wires are not mounted in other places to the balloon surface allowing a free sliding longitudinal motion of the wires along the longitudinal axis of the balloon within the groove, upon inflation and deflation. Col. 5, lines 34-50.

Vigil et al. discloses a balloon catheter with seated cutting edges. Device 10 includes a balloon 12 positioned near the distal end 13 of a hollow catheter 14. Col. 3, lines 38-39. Balloon 12 includes, as shown in FIG. 1, a plurality of substantially identical atherotomes 28a, 28b, 28c mounted on outer surface 18 of balloon 12 aligned along the longitudinal axis of catheter 14 and circumferentially equidistant from each adjacent atherotome. Col. 4, lines 8-12.

Kaplan et al. discloses an intravascular catheter for administering a therapeutic agent to a treatment site in the wall of a vessel. Col. 3, lines 51-54.

Amended Claim 1 is patentable by calling for a balloon catheter for performing an angioplasty procedure on a lesion in a vessel of the type set forth therein having, among other things, at least one flexible elongate element extending over the outer surface of the balloon from the proximal extremity to the distal extremity of the balloon, said flexible elongate element having proximal and distal extremities fixed longitudinally relative to the catheter shaft at respective positions proximally and distally of the outer surface of the balloon whereby expansion of the balloon causes movement of the flexible elongate element into engagement with the lesion to form a longitudinal channel in the lesion.

Contrary to any assertion of the Examiner, none of Barth, Vigil et al. or Kaplan et al. discloses a balloon catheter having a flexible elongate element secured in fixed longitudinal positions about the proximal and distal extremities of the catheter shaft spaced longitudinally away from the outer surface of the balloon.

Claims 3-4 have been cancelled, without prejudice. Claims 2 and 5-15 and new Claim 20 depend from Claim 1 and are patentable for the same reasons as Claim 1 and by reason of the additional limitations called for therein. For example, Claim 5 is additionally patentable by stating that at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material to permit stretching of the flexible elongate element during inflation of the balloon and retraction during deflation of the balloon, while Claim 6 is additionally patentable by stating that both of the proximal and distal extremities of the flexible elongate element are formed of an elastic material. Claim 15 is additionally patentable by calling for a balloon catheter as in Claim 2 wherein said flexible elongate elements are formed as a part of a

cage mounted over the balloon and including first and second spaced apart rings secured to the flexible elongate elements, said rings being spaced apart a sufficient distance so that the outer surface of the balloon can engage the flexible elongate elements, said rings being sized so that the cage is slidably mounted on the catheter shaft and permitting the cage to be slipped onto and over the balloon when the balloon is in a deflated condition and serving to retain the flexible elongate members in engagement with the balloon during inflation of the balloon. None of the cited references discloses the additional limitations of Claims 5, 6 and 15.

New Claim 21 is different in scope than the claims of record and patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel comprising a flexible elongate catheter shaft having proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having an inflatable portion provided with an interior, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity and opening into the interior of the balloon adapted to supply the inflation medium to the interior so as to permit inflation of the balloon, and at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon whereby upon inflation of the balloon the flexible elongate element is moved into engagement with the lesion to form a longitudinal channel in the lesion. None the cited references discloses at least one flexible elongate element secured to the catheter shaft proximal and distal of the inflatable portion so as to extend longitudinally over the inflatable portion of the balloon and be in longitudinal tension over the inflatable portion of the balloon.

New Claims 22-24 depend from Claim 21 and are patentable for the same reasons as Claim 20 and by reason of the additional limitations called for therein.

New Claim 25 is different in scope than the claims of record and patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel comprising a flexible elongate catheter shaft having proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having an inflatable portion provided with an interior, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity and opening into the interior of the balloon adapted to supply the inflation medium to the interior so as to permit inflation of the balloon, and at least one flexible elongate element having a proximal extremity secured to the catheter shaft proximal of the inflatable portion and a distal extremity secured to the catheter shaft distal of the inflatable portion whereby upon inflation of the balloon the flexible elongate element is moved into engagement with the lesion to form a longitudinal channel in the lesion, at least one of the

proximal and distal extremities of the flexible elongate element being formed of an elastic material to permit stretching of the flexible elongate element during inflation of the balloon. None of the cited references discloses a balloon catheter of the type called for in Claim 24 in which at least one of the proximal and distal extremities of the flexible elongate element is formed of an elastic material to permit stretching of the flexible elongate element during inflation of the balloon.

New Claim 26-27 depend from Claim 25 and are patentable for the same reasons as Claim 24 and by reason of the additional limitations called for therein.

New Claim 28 is different in scope than the claims of record and patentable by calling for a balloon catheter for use with an inflation medium to perform an angioplasty procedure on a lesion in a vessel comprising a flexible elongate catheter shaft having proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having proximal and distal extremities and an inflatable portion provided with an interior, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity of the catheter shaft and opening into the interior of the balloon adapted to supply the inflation medium to the interior so as to permit inflation of the balloon, and a cage slidably mountable on the catheter shaft so as to overlie the inflatable portion of the balloon, the cage having a plurality of circumferentially disposed flexible elongate elements and first and second spaced-apart rings, the first ring being secured to the flexible elongate elements and positioned about the catheter shaft in the vicinity of the proximal extremity of the balloon and the second ring being secured to the flexible elongate elements and positioned about the catheter shaft in the vicinity of the distal extremity of the balloon whereby upon inflation of the balloon the flexible elongate elements are moved by the inflatable portion into engagement with the lesion to form a longitudinal channel in the lesion.

None of the cited references discloses a balloon catheter of the type called for in Claim 27 having a cage slidably mountable on the catheter shaft so as to overlie the inflatable portion of the balloon, the cage having a plurality of circumferentially disposed flexible elongate elements and first and second spaced-apart rings, the first ring being secured to the flexible elongate elements and positionable about the catheter shaft in the vicinity of the proximal extremity of the balloon and the second ring being secured to the flexible elongate elements and positionable about the catheter shaft in the vicinity of the distal extremity of the balloon.

New Claim 29 depends from Claim 28 and is patentable for the same reasons as Claim 27 and by reason of the additional limitations called for therein.

New Claim 30 is different in scope than the claims of record and patentable by calling for a balloon catheter for performing medical procedure on a lesion in a vessel comprising a flexible

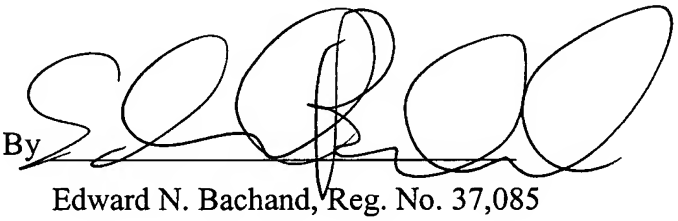
elongate catheter shaft having proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having an inflatable portion provided with an interior, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity and opening into the interior of the balloon and adapted to supply the inflation medium to the balloon interior so as to permit inflation of the balloon, and at least one flexible elongate element detached from and extending over the inflatable portion of the balloon, said at least one flexible elongate member secured to the catheter shaft proximal and distal of the inflatable portion.

New Claim 31 depends from Claim 30 and is patentable for the same reasons as Claim 30 and by reason of the additional limitations called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

DORSEY & WHITNEY LLP

By 

Edward N. Bachand, Reg. No. 37,085

Four Embarcadero Center, Suite 3400
San Francisco, CA 94111-4187
Telephone: 650-494-8700

1076137